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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION	Lead Case No.: 3:21-cv-03825-VC
THIS DOCUMENT RELATES TO: ALL ACTIONS	**OPPOSITION OF DEFENDANT INTUITIVE SURGICAL, INC. TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND CROSS-MOTION FOR SUMMARY JUDGMENT** Hearing Date: June 8, 2023 Hearing Time: 1:00 p.m. Hearing Place: Courtroom 5 Judge: The Honorable Vince Chhabria

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NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on June 8, 2023, at 1:00 PM, or as soon thereafter as available, in the courtroom of the Honorable Vince G. Chhabria, at 450 Golden Gate Avenue, Courtroom 5, 17th Floor, San Francisco, CA 94102, Defendant Intuitive Surgical, Inc. ("Intuitive") will and hereby does move for an order granting summary judgment in favor of Intuitive on plaintiffs' complaint. This Motion is based on the Memorandum of Points and Authorities provided below, the accompanying Declarations of Kathryn Cahoy, Dave Rosa, Ron Bair, and Loren Smith, with attached exhibits, any reply or other supplemental briefing and/or evidence submitted, and the oral argument of counsel.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND STATEMENT OF ISSUES

Plaintiffs bring this suit because Intuitive objected when third parties tried to hack into Intuitive's complex, precision surgical instruments to bypass use limits on the instruments that were carefully designed and tested by Intuitive and cleared by the Food & Drug Administration ("FDA") to protect the health and safety of surgical patients. Intuitive has taken the position that the modification of its instruments for this purpose cannot lawfully occur without FDA clearance. FDA agrees and has repeatedly said so.

Plaintiffs – resting on arguments that have been rejected repeatedly by FDA (and in one instance by the Ninth Circuit) – assert that FDA clearance for this activity is *not* required – or, at least, that the question should be viewed as so ambiguous that third parties are free to engage in this activity. They claim that FDA clearance is not required because these third parties refer to the activity as "repair" rather than "remanufacturing." But the modifications, far from "repairing" any malfunction, are made to *prevent* the devices from operating as designed, and the FDA has for nearly a decade been telling everyone who asks – and some who choose not to – that this activity is remanufacturing for which clearance is required.

The parties appear to agree on one thing: that the question of whether FDA clearance is required for these modifications of Intuitive's EndoWrists presents a legal issue that the Court should decide. No one disputes that the statute and regulations require FDA clearance for remanufacturing; the regulations

say what remanufacturing is; the undisputed record shows what the modifications at issue consist of; and regardless of whether, as plaintiffs suggest, the line between "remanufacture" and "repair" is unclear in *other* contexts, it is perfectly clear here, as FDA has been saying repeatedly for nearly a decade.

Because the "competition" that plaintiffs complain should have existed was barred by the applicable regulatory regime, plaintiffs cannot establish causation of antitrust injury. Their causation case – both for their primary claim on EndoWrists and their secondary claim relating to "service" of da Vinci systems – fails on other grounds as well on the undisputed record, including the fact that these plaintiffs had no actual interest in the products and services they now complain were lacking.

Plaintiffs' antitrust claims also fail for another fundamental reason: Intuitive had legitimate justifications for protecting the use limitations embodied in FDA's clearance of its devices. The antitrust laws condemn only *unreasonable* restraints of trade. *Ohio v. Amer. Express Co.*, 138 S. Ct. 2274, 2284 (2018). The undisputed record demonstrates that Intuitive's conduct relating to EndoWrists, which sought to effectuate patient-protection measures approved by the pertinent regulatory authority, was reasonable. Similarly, there is nothing anticompetitive about its contract provisions on service, which impose no meaningful restraint on competition.

None of the other issues raised in plaintiffs' motion are suitable for disposition on summary judgment. As explained in detail in the reports of Intuitive's economic expert, plaintiffs' arguments about market definition and monopoly power are inconsistent with basic economic principles and there is plentiful evidence in the record that the "relevant markets" for plaintiffs' claims are significantly different from what plaintiffs contend. Plaintiffs have not challenged the qualifications, methodology, or opinions of Intuitive's expert; his testimony alone renders summary judgment inappropriate. Evidence in the record also contradicts plaintiffs' assertion that Intuitive possesses market power, as economic theory and the relevant case law define that term. In any event, these questions should be moot, as Intuitive is entitled to summary judgment on *other* grounds, as set forth below.

II. STATEMENT OF UNDISPUTED FACTS

A. The Da Vinci

Intuitive manufactures sophisticated medical devices used to perform surgery. Its da Vinci systems are often referred to as "robotic" surgical systems, as they allow a surgeon to operate from a

console that permits the surgeon to control "EndoWrist" surgical instruments attached to mechanical arms suspended above the patient. Rosa Dec. ¶ 9. EndoWrists are inserted through small incisions and can perform extremely precise, fine-tuned movements, allowing surgery to be done in a "minimally invasive" manner. The surgeon views the activity through a video feed from a tiny camera mounted on one of the arms. *Id.* Da Vinci systems allow surgeons to perform procedures with significantly reduced trauma and improved patient outcomes compared with other modes of surgery, including fewer complications and faster recovery times. *Id.*

The first da Vinci systems were introduced commercially in the United States in 2000, after years of innovation and exhaustive testing, followed by detailed review by FDA, which classifies a da Vinci system and the instruments used with it as Class II medical devices that require FDA "510(k)" clearance before they can be marketed and used on patients. *Id.* ¶ 8; *see* Cahoy Dec. Ex. 1 ¶¶ 142, 146. FDA has granted Intuitive 510(k) clearance for all EndoWrists used with da Vinci systems. That FDA clearance, and the resulting labeling of the devices, reflect use restrictions developed through extensive testing and reviewed by FDA for reasonable assurance of safety and effectiveness. Rosa Dec. ¶ 23; Cahoy Dec. Ex. 1 ¶ 75-76.

Like many innovative products, da Vinci systems have evolved over time, and Intuitive has introduced new models from time to time, with support eventually being phased out for outdated models. The "Si" systems were introduced in 2009; Intuitive ceased selling new Si systems in the United States in 2018 and is expecting to cease support for those systems, including the sale of new S/Si EndoWrists, in 2024, ten years after introducing the successor Xi model. Rosa Dec. ¶ 11; Cahoy Dec. Ex. 2 at 172:13-174:12. The models that are primarily used today in the United States are the Xi, introduced in 2014, and the X, introduced in 2017. Rosa Dec. ¶ 11. The X and Xi systems use Generation 4 EndoWrists; the S and Si systems use older-design Generation 3 EndoWrists. *Id.* Intuitive has numerous patents on innovations embodied in da Vinci systems and EndoWrists. *Id.* ¶ 12.

B. Use Limits on EndoWrists

One of the primary innovations of the da Vinci is the unique design of EndoWrists, which mimic and even exceed the range of motion of the human wrist, allowing the surgeon to move an instrument easily inside the body to desired angles with great precision. Rosa Dec. ¶ 24. This feature requires use

of fine wire cables that thread through a complex pulley system. *Id.* This design gives the surgeon tremendous flexibility, but at the cost of making the instruments susceptible to wear and tear with repeated use. Unlike traditional surgical instruments, EndoWrists can fail after only a modest number of uses. *Id.* ¶ 27. Failure can occur in multiple ways, including (among others) metal fatigue of the fine wire cables, breaks in the intricate pulley system, and failure of the apparatus to maintain the needed precision of movement. *Id.*; *see* Cahoy Dec. Ex. 3 ¶¶ 36, 75, Ex. 4 at 38:17-47:12. The result of such failures mid-surgery can range from modest (requiring the instrument to be withdrawn from the body and replaced) to serious (if, for example, tiny pieces fall into the body) to catastrophic (if, for example, the wrist feature fails and leads to unwanted motion just as the surgeon is performing a task adjacent to a major blood vessel). Rosa Dec. ¶ 27; *see also* Cahoy Dec. Ex. 9 at 48:21-51:25, Ex. 5 at 55:3-25, Ex. 4 at 165:7-169:13, Ex. 93 ¶¶ 20, 42.

Because of the potential implications of EndoWrist failure, the useful life of EndoWrists has long – going back more than 20 years – been a focus of exhaustive testing programs, which formed the foundation for the required safety demonstrations to FDA. Rosa Dec. ¶ 28. It was clear from the beginning that use limits would be needed for EndoWrists, with a reasonable margin of safety. The nature and extent of those limits required evaluation, not just of the wear and tear the instruments would experience in typical surgical procedures, but also of the stresses associated with the rigorous cleaning and sterilization processes required for each use. *Id.* ¶ 9; *see also* Cahoy Dec. Ex. 3 ¶¶ 41, 121-22. Over a period of years, Intuitive performed extensive testing on EndoWrists to evaluate the number of uses that could be tolerated without exceeding statistical targets for failure. Rosa Dec. ¶¶ 29; *see* Cahoy Dec. Ex. 5 at 31:9-32:15. The resulting data, along with the use limits generated based on the data, were submitted to FDA in Intuitive's 510(k) submissions, with the use limits identified as prerequisites for the regulatory clearance that was sought and granted. Rosa Dec. ¶ 31; Cahoy Dec. Ex. 1 ¶¶ 75-101.[1]

[1] Plaintiffs assert that the use limits were "set by Intuitive's marketing department, not its engineers." Pl. Mot., Dkt. No. 127, at 6. That assertion is both false and a red herring. Intuitive's marketing group (and in particular the clinical marketing subgroup that promoted efforts to tailor the product to customer needs) provided input on the use limits that were selected – but the primary content of that input, particularly in the early days, was strong encouragement to redesign EndoWrists under development to allow *more* uses than early testing supported. Rosa Dec. ¶ 32; Cahoy Dec. Ex. 5 at 35:9-36:19. Most

EndoWrists were described to, and cleared by, FDA as "limited use" instruments containing use counters that cause each EndoWrist to cease functioning after its final cleared use. Rosa Dec. ¶ 31; Cahoy Dec. Ex. 1 ¶¶ 75-101, Ex. 6, Ex. 7. For most S/Si instruments, Intuitive proposed, and FDA cleared, a limit of ten uses. Rosa Dec. ¶ 33.

Each EndoWrist contains a computer chip that tracks critical information about the instrument, including the number of times it has been used. *Id.* ¶ 36. The chip is programmed to render the instrument nonfunctional after it has had the maximum allowed number of uses. *Id.* This prevents a user from inadvertently (or otherwise) exceeding the number of approved uses for the instrument. *Id.* The computer chip used for this purpose in S/Si EndoWrists is called the "Dallas" chip and communicates with the da Vinci system through a physical connection. *Id.* ¶ 37; Cahoy Dec. Ex. 8 at 108:24-109:15, Ex. 9 at 20:1-21:5. For X/Xi systems, Intuitive upgraded to a wireless connection; this required the chip to be encrypted for security purposes to avoid tampering. Rosa Dec. ¶ 37; Cahoy Dec. Ex. 8 at 121:14-122:7, Ex. 9 at 22:5-21, 30:9-17, 40:13-41:1.

Plaintiffs possess no evidence to dispute that EndoWrists are subject to failure from wear-and-tear; nor do they have evidence that EndoWrists can reliably be used indefinitely. Instead, the most their technical expert offers is speculation that this safety issue could instead have been managed through some kind of complex monitoring of the specific length of time during which each instrument is used and the actions performed with it. This opinion is the subject of a pending *Daubert* motion. *See* Dkt. No. 124. And even plaintiffs' expert is unable to dispute that (a) the use limits were preceded by years of exhaustive safety testing, (b) that they were cleared by FDA, and (c) nothing in Intuitive's decades of testing data indicates that EndoWrists could consistently be used safely and reliably for a substantially greater number of uses than they were cleared for. *See* Cahoy Dec. Ex. 3 ¶¶ 64-72, Ex. 1 ¶¶ 75-101.

C. Intuitive's Sales to Hospitals

The hospitals and surgery centers that purchase da Vinci systems are highly sophisticated consumers. A sale of a da Vinci is routinely preceded by extensive presentations on the costs and benefits to the hospital of having a da Vinci available as an alternative modality for performing many

importantly, the undisputed record shows that the use limits were validated by years of testing performed by Intuitive's engineers.

types of surgery. Rosa Dec. ¶ 14; *see, e.g.*, *id.* Ex. 1. For the hospital, the surgeon, and the patient, the choice between surgical modalities considers a variety of factors, including cost. Smith Dec. Ex. 1 ¶¶ 19, 111. The cost analysis for the hospital includes ongoing costs for EndoWrists and accessories used with the system. Rosa Dec. ¶ 14; *see* Cahoy Dec. Ex. 33 at 63:17-64:7. Hospitals are fully aware when they purchase a da Vinci that its EndoWrists are limited use devices that will require replacement after a fixed number of uses. Rosa Dec. ¶ 20.

Each purchaser or lessor of a da Vinci enters into a contract with Intuitive, typically a Sales, Licensing and Service Agreement ("SLSA") or corresponding lease agreement, but the terms of those contracts are heavily negotiated. *See id.* ¶ 21; *see also* pp. 11-12 below (discussing plaintiffs). Although the language of the contracts varies, they typically prohibit customers from modifying, altering, or misusing the system and its components or manipulating the software. *See, e.g.*, Cahoy Dec. Ex. 11 at -5489-90 (§§ 3.4, 4, 5.2), Ex. 12 at -6316, -6318 (§§ 4, 5.2), Ex. 13 at -0653-54 (§§ 3.4, 4, 5.2). The agreements confirm that the da Vinci system should be used only with approved EndoWrists and provide that use of a non-approved instrument may give Intuitive the right to discontinue service. Intuitive also disclaims warranty obligations for claims arising from repairs, modifications, or other changes made by a third party. *E.g.*, *id.* Ex. 11 at -5490-91 (§§ 5.2(E), 10.1), Ex. 12 at -6318, -6320 (§§ 5.2(E), 10.1), Ex. 13 at -0654-56 (§§ 5.2(E), 10.1).

D. Third-Party Modifications of EndoWrists to Hack the Use Counters and Reactions from FDA

Sometime around 2014, a company called Rebotix decided it wanted to create a new business by hacking into EndoWrists to defeat the use counters.[2] Rebotix developed a computer chip called the "Interceptor" that could be inserted inside an Si EndoWrist to "intercept" the data in the Dallas chip's memory and fool the system into accepting a new use count starting at zero. *See id.* Ex. 14 at -1000. However, [redacted]

[2] There have been multiple affiliated entities operating under various iterations of the "Rebotix" name; for purposes of simplicity they are all referred to here as "Rebotix." Similarly, the names "Restore" and "Iconocare" are used to refer collectively to entities that operated with versions of those respective names and/or shared common ownership with those companies.

[redacted] *See id.* Ex. 15 at -2418-23. For example, [redacted] *See id.* at -2421-22; Cahoy Dec. Ex. 16 at 238:7-11.[3] Although Rebotix advertised that this reset could be performed multiple times to extend an instrument's life indefinitely in increments of 10, *see id.* Ex. 19 at 65:6-11, Ex. 20 at 171:1-8, 176:13-177:22, the record is devoid of testing data to confirm the accuracy of this claim.

In December 2014, Rebotix applied to FDA for regulatory clearance of its Interceptor procedure as permissible "remanufacturing" of EndoWrists. *See id.* Ex. 1 ¶ 103, Ex. 21. FDA identified substantial deficiencies in Rebotix's application, including an absence of sufficient safety testing data given "the fact that the device is not simply a reusable device, but is a third party reprocessed/remanufactured device." *Id.* Ex. 22 at -7733. Meanwhile, FDA warned Rebotix that it could not place remanufactured EndoWrists into commercial distribution until and unless it received the agency's permission to do so. *Id.* Ex. 23, Ex. 1 ¶ 107.

Rather than addressing the deficiencies identified by FDA, Rebotix withdrew its application. *Id.* Ex. 24. Rebotix moved to Panama and offered its modified instruments to customers outside the United States, beyond the jurisdiction of FDA. *Id.* Ex. 20 at 49:3-50:14. But after those operations were enjoined abroad, Rebotix decided to try again in the United States. *See id.* Ex. 25 at -2749, Ex. 26 at 166:5-12. Rebotix's new business model, beginning in 2018, was for hospitals to retain ownership of their used Si EndoWrists and hire Rebotix to modify the instruments. *See id.* Ex. 20 at 210:9-21, 227:10-23. Although the modification was identical to the remanufacturing process for which Rebotix had previously acknowledged the need for FDA clearance, Rebotix told customers that a loophole in the

[3] Plaintiffs make much (Pl. Mot. at 24) of a program that Intuitive considered instituting through which it would itself refurbish used EndoWrists. What plaintiffs neglect to mention is that this program contemplated *full* refurbishment of the instruments, including replacing the cables and other sensitive parts that were prone to failure after multiple uses. Rosa Dec. ¶ 38; Cahoy Dec. Ex. 17 at 40:7-12. Intuitive abandoned the project when it determined that the cost of proper refurbishment would make the project not commercially feasible. Rosa Dec. ¶ 39; Cahoy Dec. Ex. 18 at 172:23-173:20. Neither Rebotix nor any other third party offered this kind of genuine refurbishment.

law allowed the clearance process to be skipped if legal title to the used instruments did not change. *Id.* at 212:15-218:8; Cahoy Dec. Ex. 27 at -4230. As discussed further below, this was wrong.

Rebotix entered into a relationship with Restore Robotics ("Restore"), which was to market the Rebotix process to hospitals, buy the Interceptor chips from Rebotix, and modify the instruments. *See id.* Ex. 28 at -0713-23. Restore performed these functions for several months, but Rebotix terminated the contract in late 2019. *Id.* Ex. 20 at 132:12-21. Rebotix also entered into an arrangement with Surgical Instrument Service Company ("SIS"), under which SIS would market the Rebotix service to hospitals and Rebotix would perform the modifications. *Id.* Ex. 29 at 19:2-8, 33:22-34:4. Rebotix modified a handful of EndoWrists for SIS before the two companies stopped working together. *Id.* Ex. 30 at 56:24-57:18, Ex. 77 at 25:25-26:5, 71:12-24, Ex. 92.

In May 2018, a Rebotix distributor reached out to FDA for clarification after potential customers expressed concern about the lack of FDA clearance for the Rebotix process. *Id.* Ex. 31 at -0336, Ex. 20 at 219:13-24. Consistent with FDA's prior communications to Rebotix, FDA confirmed that 510(k) clearance was indeed required, because "if the use-life counter is reset or extended past the number of available use lives, then the device specifications are changed," which would constitute "remanufactur[ing]." *Id.* Ex. 31 at -0335; *see id.* Ex. 32. In February 2020, FDA emailed Rebotix directly, confirming that "a 510(k) is needed before [Rebotix] continue[s] [its] operation." *Id.* Ex. 34 at -6955.

FDA contacted Rebotix again in November 2021, stating that it had received information that Rebotix "may be remanufacturing the da Vinci S EndoWrist Instruments," and seeking further information. *Id.* Ex. 35 at -5417. Rebotix then engaged in an effort to persuade FDA that it did not need 510(k) clearance; those efforts were unsuccessful. *See id.* Ex. 36, Ex. 37. FDA wrote to Restore as well, stating that "a 510(k) is needed before you continue your operation," and seeking more information on Restore's activities. *Id.* Ex. 1 ¶ 220, Ex. 38 at -1256. Rather than respond, Restore informed the agency that it had elected to exit the business. *Id.* at -1249.

Restore then enlisted a third party, Iconocare, to develop an alternative technology for resetting Si EndoWrists and – bowing to the inevitable – to submit an application for FDA clearance. Cahoy Dec.

Ex. 39 at 204:16-205:17, 213:19-216:23.

. *Id.* at 213:9-25; Cahoy Dec. Ex. 3 ¶¶ 143-52.

That application was limited to just *one* reset (adding ten additional uses but no more) of *one* Si EndoWrist model. *Id.* Ex. 40 at -7816-18.

. *Id.* Ex. 1 ¶¶ 127, 134, Ex. 41 at -0535, Ex. 42 at -6093.

Rebotix and Restore have both attempted to bypass the encryption in later-generation X/Xi EndoWrists for purposes of modifying those instruments to reset their use counters. Those efforts have been pursued over several years, but the most recent evidence indicates they have not succeeded. *Id.* Ex. 96 at 60:15-18, Ex. 94 at 8:13-9:4, 10:9-11:1, Ex. 95 at 31:15-32:1. There is no evidence in the record that *anyone* has ever developed or offered to sell a method to reset use counters on X/Xi EndoWrists; nor has anyone sought or received FDA clearance for such a process.

E. Da Vinci Service

A da Vinci is a complex and sophisticated system that requires regular preventative maintenance, as well as occasional service to deal with malfunctions. Bair Dec. ¶ 4. Intuitive offers annual service contracts to cover all these needs; prices for these contracts (after the first year, when it is included in the purchase price) are negotiated individually with each customer. *Id.* ¶ 5. The vast majority of customers choose to enter into service contracts. However, customers are not obligated to enter into service contracts and can perform some basic service functions in-house or using third parties. *Id.* Intuitive makes "as needed" service available upon demand on a time and materials basis. *Id.*

Proper servicing for a da Vinci requires proprietary tools and instruments (the "toolkit") and proprietary software and procedures to diagnose problems and guide the technician in addressing them. *Id.* ¶ 7. Intuitive does not make these items available to third parties in the United States, *id.*, and it is undisputed that it has no legal obligation to do so. *See* Order, Dkt. No. 69, at 2.

In 2018, Restore briefly embarked on an effort to market servicing for Si systems. Cahoy Dec. Ex. 43 at 48:5-16, 115:8-23. It hired two former Intuitive service technicians who had some knowledge of Si systems. *Id.* at 114:10-17. There is no evidence that any other entity has ever claimed an ability to perform service on da Vinci systems, and Restore never attempted to service X or Xi systems. Cahoy Dec. Ex. 44 at 102:4-103:23; *see id.* Ex. 29 at 92:12-14.

Restore did not have access to the proprietary toolkit for servicing a da Vinci and lacked the technical ability to perform most servicing activities. *Id.* Ex. 44 at 140:13-141:25, 166:17-25, 229:18-22, Ex. 43 at 109:17-110:5. Its technicians quickly encountered difficulty in performing even basic maintenance, and its customers ended up asking Intuitive to fix problems Restore had created. *See* Bair Dec. ¶¶ 10-19. Restore ceased its service business shortly thereafter. Cahoy Dec. Ex. 43 at 118:5-8; *cf. also id.* Ex. 45 at 29:1-6, 33:23-34:21, 35:13-17.

F. Intuitive's Response to the Activities of Rebotix and Restore

Intuitive first became aware of third parties modifying Si EndoWrists through customer returns of broken EndoWrists.[4] An Intuitive team that is responsible for failure analysis disassembled some of the returned instruments and discovered that they had been modified with the insertion of what Intuitive later learned were Rebotix Interceptor chips. Rosa Dec. ¶ 41; Cahoy Dec. Ex. 5 at 76:4-17, Ex. 9 at 35:17-22.

Intuitive began to reach out to customers who were using remanufactured EndoWrists, explaining that the use limits are grounded in extensive safety testing, and that resetting the use counters could create significant safety concerns for patients. Intuitive expressed the view that such modifications required FDA clearance. Intuitive also pointed out that use of remanufactured devices without the required FDA clearances would violate customers' contracts with Intuitive. Rosa Dec. ¶¶ 42-43 & Ex. 2 at -0926-27.

The record contains no evidence that Intuitive has interfered in any way with EndoWrist modification efforts done pursuant to a duly issued FDA clearance. To the contrary, to avoid any

[4] As part of its commitment to quality and regulatory obligations, Intuitive maintains a Returned Materials Authorization ("RMA") process that provides liberal "no questions asked" warranty coverage for EndoWrists that are returned for almost any reason other than clear and unmistakable abuse. Rosa Dec. ¶ 40. Returned devices are carefully evaluated to assess and track the causes of any failures. *Id.*

possibility of confusion, Intuitive has made clear that use of an FDA-cleared remanufactured EndoWrist does not breach any customer's contract or otherwise subject a customer to adverse action from Intuitive. *Id.* ¶ 45. Intuitive continues to take the position that tampering with an EndoWrist to reset its use counter through any means *not* cleared by FDA is both unlawful and potentially dangerous. *Id.* ¶ 46.

G. Plaintiffs

Plaintiff Larkin Community Hospital ("Larkin") operates two hospitals in Florida. Cahoy Dec. Ex. 46 at 11:8-12:6. In 2017, it leased two da Vincis, an Si and an Xi. *Id.* Ex. 11 at -5496-97. Its lease agreements for these systems were the subject of extensive negotiations, through which Larkin obtained nearly $500,000 in discounts. *Id.* Ex. 46 at 100:4-15, Ex. 63 at -9070. Larkin returned its Si system to Intuitive in 2022 and currently has only an Xi system. Bair Dec. ¶ 9.

Plaintiff Franciscan Alliance ("Franciscan") operates 13 hospitals in the Midwest. Cahoy Dec. Ex. 47 at 23:13-15. It previously owned several da Vinci Si systems, but it replaced them over time between 2015 and 2020 and currently operates only da Vinci Xi systems. *Id.* at 116:25-117:2; Cahoy Dec. Ex. 48 at 13-14. Its procurement of da Vinci systems was preceded by detailed financial analyses and negotiations with Intuitive, through which it was able to achieve significant concessions on price and other terms. *Id.* Ex. 49 at 29:6-22, 37:9-19, 38:7-42:1, Ex. 47 at 101:16-102:12.

Plaintiff King County Public Hospital District Number 1, DBA Valley Medical Center ("Valley") traded in its only Si system in 2019 and currently owns two Xi systems. *Id.* Ex. 50 at 43:12–44:1, 135:23–136:5. Its purchase of da Vinci systems has been preceded by extensive internal analysis, and its contracts with Intuitive have been heavily negotiated. *Id.* Ex. 51 at 110:4-7, 114:25-116:8, Ex. 50 at 43:12-44:1, 108:25-113:15, 118:6-120:21.

All three plaintiffs' contracts with Intuitive were the subject of detailed negotiations, including redlining of drafts. *E.g.*, *id.* Ex. 46 at 111:3-116:18, Ex. 52. In the one instance where a plaintiff – Franciscan – objected to a provision that prohibited Franciscan from "permit[ting] any third party to[] modify, disassemble, reverse engineer, alter, or misuse the System or Instruments and Accessories," Intuitive agreed to the revision. *Id.* Ex. 47 at 82:9-86:7, Ex. 52 at -2151, Ex. 12 at -6315. There is no evidence that any of the plaintiffs otherwise objected to the contract provisions that prohibited unauthorized modification of Intuitive products or the use of unapproved instruments with the systems.

Id. Ex. 46 at 111:3-116:18, Ex. 47 at 95:14-98:5, Ex. 52, Ex. 53, Ex. 54, Ex. 55, Ex. 56, Ex. 57, Ex. 58, Ex. 50 at 107:10-108:24, Ex. 13.

None of the three plaintiffs sought to use remanufactured EndoWrists. A Franciscan administrator received information about Rebotix's offering, but it was not "top of mind" and she set it aside. *Id.* Ex. 59 at 35:16-22, 36:4-17, 41:17-42:17. Larkin had discussions with a distributor offering the Rebotix service but perceived it as "shady" and was concerned about the lack of FDA clearance. *Id.* Ex. 60 at 57:24-58:7. Valley's 30(b)(6) witness testified that he was unaware of any approach from a third party. *Id.* Ex. 61 at 42:3-14.

Nor did any of the plaintiffs seek to use a third party to service their da Vinci systems. Larkin's director of surgery thought it "made no sense" to have Larkin's "extremely delicate" systems serviced by anyone other than Intuitive, and he did not recall Larkin ever having any interest in using a third party. *Id.* Ex. 62 at 55:12-57:12; *see also id.* Ex. 59 at 43:13-45:1 (discussing information and assurances Franciscan would have needed before considering a third-party servicer), Ex. 61 at 39:14-22 (Valley has never considered using a third party to service its da Vinci systems). Franciscan and Valley had long-term service contracts with Intuitive throughout the relevant period; Larkin had a service contract for part of the period. Bair Dec. ¶ 9.

III. ARGUMENT

Rule 56 "mandates the entry of summary judgment … against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "When the nonmoving party has the burden of proof," the movant need only show "an absence of evidence to support the nonmoving party's case." *Devereaux v. Abbey*, 263 F.3d 1070, 1076 (9th Cir. 2001). When the opposing party identifies evidence of a genuine dispute of fact material to a legal issue presented, summary judgment must be denied. *Lopez v. Smith*, 203 F.3d 1122, 1131 (9th Cir. 2000).

Plaintiffs' operative complaint, Dkt. No. 52, asserts six causes of action under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2. Each cause of action has distinct requirements, but all have in common two elements addressed in Intuitive's cross-motion here: (1) The alleged antitrust violations

must have been a proximate cause of injury to plaintiffs and (2) defendant's challenged conduct must have been lacking in non-pretextual legitimate justifications.

On the additional issues raised in plaintiffs' motion for summary judgment – the elements of market definition and market power – the record contains critical disputes of material fact. Plaintiffs' motion should accordingly be denied. The Court need not reach those issues, however, as they should be mooted by entry of summary judgment for Intuitive.

A. Plaintiffs Cannot Establish that Intuitive Caused Them Antitrust Injury in Their Purchase of EndoWrists.

A necessary element of any antitrust claim is proof of proximate causation of antitrust injury. *Atlantic Richfield Co. v. USA Petrol. Co.*, 495 U.S. 328, 334 (1990); *Ass'n of Washington Pub. Hosp. Dists. v. Philip Morris Inc.*, 241 F.3d 696, 701 (9th Cir. 2001). Antitrust injury is that which "flows from that which makes the conduct unlawful" and "is of the type the antitrust laws were intended to prevent." *City of Oakland v. Oakland Raiders*, 20 F.4th 441, 456 (9th Cir. 2021).

Proximate causation of antitrust injury to these plaintiffs is lacking here for multiple reasons, including (among others): (1) that the governing regulatory scheme precluded the "competition" through remanufacturing of EndoWrists that plaintiffs claim should have existed; (2) that these plaintiffs had no interest in using remanufactured EndoWrists; and (3) insofar as plaintiffs' claims relate to X/Xi EndoWrists, no potential competitor has ever had the ability to re-set those devices.

1. The Governing Regulatory Scheme Precluded the "Competition" from Remanufactured EndoWrists that Plaintiffs Complain Was Lacking.

There is no evidence that anyone other than Intuitive has ever had the desire or physical ability to manufacture and sell new surgical instruments that work with da Vinci systems. Instead, plaintiffs' claims about restraints on competition in an alleged "market" for EndoWrists focus *solely* on their inability to hire third parties to modify Intuitive EndoWrists to hack their use counters. One of the fundamental problems with this theory is that, with one narrow and very recent exception not relevant here, no third party has had the legal ability to perform such modifications. Antitrust injury cannot be proved where the claimed injury "is caused by a regulatory scheme rather than by the defendant's actions," as it is "beyond fair dispute" that "a regulatory or legislative bar can break the chain of causation in an antitrust case." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d

132, 165-66 (3d Cir. 2017); *Modesto Irrig. Dist. v. Pac. Gas & Elec. Co.*, 309 F. Supp. 2d 1156 (N.D. Cal. 2004), *aff'd*, 158 F. App'x 807 (9th Cir. 2005).[5]

For example, in *Modesto*, the plaintiff, an irrigation district, complained that PG&E had interfered with its attempt to offer competing electric service in Pittsburg. The district court held that the plaintiff could not prove antitrust injury because it "possessed neither the legal right, nor the necessary [regulatory agency] permission to expand its service into Pittsburg." 309 F. Supp. 2d at 1170. And "[b]ecause [the plaintiff's] conduct was unlawful by its own terms, PG&E's response – however anti-competitive or seemingly monopolistic – could not inflict an cognizable antitrust injury." *Id.* The Ninth Circuit affirmed, confirming that, because it was "not a lawful competitor," the plaintiff "could not have suffered an antitrust injury at the hands of PG&E." 158 F. App'x at 807; *see also In re Wellbutrin XL*, 868 F.3d at 165 ("It is not enough for the Appellants to show that Anchen wanted to launch its drug; they must also show that the launch would have been legal.").

Similarly here, necessary regulatory clearance was lacking for the remanufacturing activity plaintiffs claim Intuitive prevented them from purchasing. It is undisputed that EndoWrists are Class II medical devices that require 510(k) clearance from FDA. Rosa Dec. ¶¶ 8, 34; Cahoy Dec. Ex. 1 ¶¶ 142-46; *see* 21 U.S.C. §§ 360(k), 360c(a)(1)(B). This requirement is equally applicable to the "remanufacture" of a device. A "remanufacturer" is defined under FDA regulations as "any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use," as reflected in the 510(k) submission for the device previously cleared by FDA. 21 C.F.R. § 820.3(w). A remanufacturer meets the definition of "manufacturer" and is thus subject to 510(k) requirements. *See* 21 C.F.R. § 820.3(o) (defining manufacturer to include anyone engaged in remanufacturing); 21 C.F.R. § 807.20 (requiring manufacturers to register and list with the FDA); 21 C.F.R. § 807.81(a)(3) (requiring

[5] *See also Snake River Valley Elec. Ass'n v. PacifiCorp*, 357 F.3d 1042, 1050 n.8 (9th Cir. 2004); *RSA Media, Inc. v. AK Media Grp., Inc.*, 260 F.3d 10, 15 (1st Cir. 2001); *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 269 (3d Cir. 1998); *In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 791 (8th Cir. 2006); *Realnetworks Inc. v. DVD Copy Control Ass'n, Inc.*, 2010 WL 145098, at *6 (N.D. Cal. Jan. 8, 2010); *Datel Holdings Ltd. v. Microsoft Corp.*, 2010 WL 3910344, at *4 (N.D. Cal. Oct. 4, 2010); *PharmacyChecker.com v. Nat'l Ass'n of Bds. of Pharmacy*, 2022 WL 347669, at *3 (S.D.N.Y. Feb. 4, 2022).

510(k) clearance for a "change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process").

None of the purported "competitors" in plaintiffs' proposed EndoWrist "market" – all of whom used Rebotix's technology – possessed 510(k) clearance for the modification of EndoWrists to override their use counters. Only one 510(k) clearance has ever been issued for such a modification, and that was to Iconocare, which in late 2022 obtained FDA clearance for a *different* technology used to perform a *single* reset of just *one* kind of Si EndoWrist. There is no evidence that Intuitive has ever done anything to interfere with Iconocare's ability to operate under that clearance. To the contrary, Intuitive made clear after Iconocare received its clearance that use of an FDA-cleared remanufacturing process to reset a use counter would not breach any customer's contracts with Intuitive. Rosa Dec. ¶ 42.[6]

For the better part of a decade – ever since the issue first arose – FDA has consistently made clear that modifications of EndoWrists to reset their use counters is remanufacturing that requires 510(k) clearance. FDA has communicated that position both to those who sought such clearance and to those who sought to evade doing so. *See* Cahoy Dec. Ex. 1 ¶¶ 215-29; *see also id.* Ex. 31 at -0335, Ex. 34 at -6955, Ex. 35 at -5417, Ex. 38 at -1256, Ex. 64 at -5712, -5727. It has repeatedly warned the latter that they should not operate without 510(k) clearance. *E.g.*, *id.* Ex. 34 at -6955, Ex. 38 at -1256, Ex. 64 at -5727.

FDA's consistency on this subject is not undercut by its statement in one communication to Rebotix that its determination was not a final *appealable* order. *See* Pl. Mot. at 20-21. In that same communication, FDA identified for Rebotix ways in which it could have the determination reduced to a form it could appeal. Cahoy Dec. Ex. 1 ¶¶ 230-31, Ex. 37 at -5839. There is no record of Rebotix having accepted that invitation. And although plaintiffs' expert tries to discount the years of consistent FDA statements by characterizing them as "not official," in her deposition she acknowledged that at least one of them fit even her definition of "official." *See* Dkt. No. 123 at 10.

[6] Plaintiffs could not claim that Intuitive prevented them from using devices remanufactured by Iconocare. None of them still had an Si system when Iconocare obtained its clearance in late 2022. *See* p. 11 above.

Those who sought to evade FDA clearance – and plaintiffs here – have offered two arguments for why FDA was wrong in saying clearance was needed. FDA has consistently rejected these arguments, and this Court should do the same. Regardless of whether the Court applies the deference ordinarily accorded FDA in the interpretation of its own regulations and governing statute, *see Young v. Community Nutrition Inst.*, 476 U.S. 974, 981-82 (1986), in this instance the agency was clearly right.[7]

First, plaintiffs argue that modifying an EndoWrist to bypass its use limits is not "remanufacturing" because it only constitutes "repair" (sometimes referred to as "service") of the instrument, which does not require 510(k) clearance. But "repair" involves fixing a broken device to return it to its original specifications, including any original restrictions or limits. *See* Cahoy Dec. Ex. 65 at 18; Ex. 1 ¶ 174. An EndoWrist with an expired use counter is not broken – it is operating exactly as designed. The purpose of the Rebotix technology was to *bypass* the use limits that were an integral part of the instrument's safety design, as cleared by FDA. It is difficult to imagine any example of an operation that more clearly fits the regulation's definition of "remanufacturing." As FDA has explained repeatedly, with the modifications performed, EndoWrists "no longer maintain the same safety and effectiveness profile as cleared with the original manufacturer's own submission" and therefore "require[] additional review to the new labeled usage limit in order to establish safety and effectiveness," Cahoy Dec. Ex. 64 at -5727, because "if the use-life counter is reset or extended past the number of available use lives, then the device specifications are changed," *id.* Ex. 31 at -0335.

Plaintiffs rely heavily in their motion on the proposition that the dividing line between repair and remanufacturing has in *some* contexts been considered ambiguous. *See* Pl. Mot. at 23-24. What they fail to acknowledge is that in *this* context, it is, and has always been, FDA's clearly stated position that the Rebotix process fits the regulatory definition of remanufacturing, which requires 510(k) clearance.

Second, plaintiffs press Rebotix's argument that it did not need to renew its failed 510(k) application because it was not *selling* the EndoWrists it remanufactured; rather, title remained with the

[7] The courts in the Florida lawsuits brought by Rebotix and Restore declined to rule on whether entities modifying EndoWrists to bypass their use counters needed FDA clearance – although they also barred the parties' FDA experts from testifying on that "legal" question. *See* Cahoy Dec. Ex. 71 at 6-8, 16, Ex. 72 at 8-9. The opinions of *these* plaintiffs' FDA expert on this issue should be excluded for the same reason, among others. *See* Dkt. No. 123.

hospitals that originally bought them. *See* Pl. Mot. at 21 n.15, 23. The requirement for FDA clearance applies to a device that is in "commercial distribution." 21 C.F.R. § 807.81(a). "Commercial distribution" is "any distribution of a device intended for human use which is held or offered for sale." 21 C.F.R. § 807.3(b). Plaintiffs claim this means a device is not in "commercial distribution" if it is not *sold* after it is modified. FDA was not moved by this argument either,[8] and the Ninth Circuit rejected this exact argument in *United States v. Kaplan*, 836 F.3d 1199, 1208-11 (9th Cir. 2016).

In *Kaplan*, the Ninth Circuit upheld the criminal conviction of a doctor for violating a parallel provision of the FDCA that prohibits "adulteration" of products that are "held or offered for sale" (the same language on which plaintiffs rely here). The doctor was taking a medical device that was cleared for only one use and, after attempting to clean it, used it in additional procedures. In appealing his conviction, he argued that his actions did not violate the statute because he was not selling the devices but was instead simply re-using devices he already owned. The Ninth Circuit disagreed, holding that the phrase "held or offered for sale" is not limited to a "sale in the strict sense." *Id.* at 1209. Instead, it covers a "commercial actor in a commercial setting, using a commercial product" intended for use to treat patients. *Id.* at 1210 ("[P]atients who paid Kaplan for the medical services he performed were also paying for the cost of products used in the course of treatment, including biopsies, and that the patients were therefore the ultimate consumers of the guides."). The Court also cited the general purpose of the FDCA in protecting health and safety as supporting its conclusion. *Id.* ("This interpretation of 'held for sale' comports with Congress's intent that the FDCA be interpreted broadly."). Similarly here, where remanufactured EndoWrists were to be used on patients, the need for 510(k) clearance could not be avoided by claiming the remanufactured instruments were not separately "sold."

Plaintiffs' arguments about the Extended Use program, through which Intuitive was recently able to establish higher use limits (as high as 18) for certain select X/Xi instruments, do not support their

[8] FDA made clear long ago that change in ownership is not pertinent to whether 510(k) clearance is needed. *See* 63 Fed. Reg. 67076, at 67077 (Dec. 4, 1998) ("FDA no longer believes that the processing, remarketing, or servicing of used devices should be characterized in terms of whether or not the processor acquires ownership of the device for purposes of resale or remarketing. FDA now believes that it may be more appropriate to identify and distinguish between the types of processing conducted on used devices on the basis of whether or not significant changes occur, or are made, in the performance or safety specifications or intended use of the finished device, as a result of the processing.").

position. *See* Pl. Mot. at 24-25. These life extensions were made possible by years of incremental improvements in the more advanced X/Xi instruments that were not applicable to the older S/Si instruments, which remain prone to earlier failure. Rosa Dec. ¶ 34; Cahoy Dec. Ex. 4 at 90:16-91:5, 134:4-135:2, 171:20-172:20, Ex. 66 at 97:6-13, 113:11-116:13, 197:15-201:3, Ex. 73 at 232:18-235:3. It is true that Intuitive originally believed it could implement these use changes through a truncated procedure (available only to original manufacturers that already have a 510(k) clearance, *not* remanufacturers) instead of seeking a new 510(k) clearance. Pl. Mot at 24; *see* Cahoy Dec. Ex. 1 ¶¶ 248-55; Rosa Dec. ¶ 34. What plaintiffs neglect to mention is that FDA *disagreed* with this judgment and directed Intuitive to present a 510(k) submission, complete with additional testing, in support of the changes. *Id.*; Cahoy Dec. Ex. 1 ¶¶ 252-55. If anything, this is further evidence that FDA takes the use limits very seriously and does not believe *anyone* can extend them in *any* way without 510(k) clearance.[9]

In sum, the absence of purported "competition" for the sale of EndoWrists in the form of third parties modifying Intuitive's products was caused by a regulatory scheme that precluded any such "competition" in the absence of regulatory clearances that no purported "competitor" possessed. Plaintiffs are accordingly unable to prove antitrust injury, and Intuitive is entitled to summary judgment.

2. There Is No Contemporaneous Evidence that These Plaintiffs Were Interested in Using Remanufactured EndoWrists.

Even if there were any legitimate question about whether FDA clearance was required, the undisputed facts show that these plaintiffs would not have used non-cleared instruments in the face of FDA's unqualified position on that question. Numerous witnesses for plaintiffs confirmed that if FDA took the position that remanufactured EndoWrists required FDA clearance they would not use them. *See id.* Ex. 67 at 51:24-52:8, Ex. 68 at 37:11-25, 43:2-8, Ex. 69 at 58:13-18. Indeed, that was precisely the concern voiced by Larkin's principal da Vinci surgeon, who found the offering "shady" and worried about the lack of clearance. *Id.* Ex. 60 at 57:24-58:7.

[9] To be clear, the Extended Use program did not involve resetting the use counters on expired instruments. It was, rather, about increasing the *original* programmed uses for certain of the most advanced instruments. Rosa Dec. ¶ 34. There was no remanufacturing involved.

Plaintiffs attempt to salvage their ability to prove causation through a speculative opinion of one of their experts that the mere existence of *someone* who might be interested in using remanufactured EndoWrists would have forced a dramatic decrease in Intuitive's prices for *all* customers. As demonstrated in Intuitive's *Daubert* motion on that expert, Dkt. No. 126 at 5-7, that opinion is completely lacking in record support and thus cannot create a fact issue. *See Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) (expert opinions not based on facts in the record cannot defeat summary judgment).

Given that these plaintiffs expressed no contemporaneous interest in remanufactured EndoWrists, they cannot prove causation of injury here. *See St. Louis Convention & Visitors Comm'n v. Nat'l Football League*, 154 F.3d 851, 862-64 (8th Cir 1998) (rejecting claim that NFL rule inflated lease terms city gave to team by precluding negotiations with other teams when city never attempted to solicit other bids); *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678, 716-17 (E.D. Pa. 2020) (brand loyalists who would not switch to generic drugs lacked antitrust injury from restrictions on generics); *see also Elison v. Amer. Bd. of Orthopaedic Surgery*, 11 F.4th 200, 208-10 (3d Cir. 2021) (surgeon who had not applied for staff privileges lacked standing to challenge surgeon privileging rule); *Amer. Express Anti-Steering Rules Antitrust Litig.*, 19 F.4th 127, 140-41 (2d Cir. 2021) (rejecting challenge to American Express increase in merchant fees from merchants who did not choose to accept Amex cards).

3. Plaintiffs' Claims Relating to X/Xi Instruments Fail for the Additional Reason that No Entity Possessed the Ability to Modify the Use Counters in Those Instruments.

For an additional, independent reason, the Court should grant summary judgment on plaintiffs' claims insofar as they seek damages based on their inability to use remanufactured EndoWrists for their X/Xi systems. It is undisputed that there has never been any entity in the marketplace with the *ability* to modify X/Xi EndoWrists to reset their use counters.[10] The use counter technology in those devices is fundamentally different than that used for S/Si EndoWrists, and technology to modify those use counters

[10] Plaintiffs here, unlike SIS in its separate case, have not claimed that Intuitive's upgrade of its X/Xi systems, including the addition of encrypted wireless communication to the X/Xi EndoWrists (which has been cited as a reason they are more difficult to hack), was itself an antitrust violation. As discussed in Intuitive's brief in the *SIS* case, the antitrust laws cannot be used to challenge product improvements. *Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 998 (9th Cir. 2010).

not only lacks FDA clearance, but it also does not exist. Given the absence of a concrete basis to conclude that "competition" from remanufacturers of X/Xi instruments would have existed in the "but-for" world, plaintiffs cannot prove causation of *any* injury, much less antitrust injury.

B. Plaintiffs Cannot Establish that Intuitive Caused Antitrust Injury In Their Purchase of Servicing for Da Vinci Systems.

It is undisputed that most servicing of a da Vinci system requires access to Intuitive's proprietary technology that was not available to any third party. And plaintiffs have conceded that Intuitive had no legal duty to make that proprietary technology available to third parties. *See* Dkt. No. 69 at 2. This concession is alone sufficient to defeat plaintiffs' servicing claims. The Court denied Intuitive's motion to dismiss on this ground because the Complaint alleged that a third party could do *some* things. *Id.* But the undisputed evidentiary record confirms that this would have made no difference *to these plaintiffs*.

None of the three plaintiffs ever sought to purchase the competitive services of which they now claim to have been deprived. Indeed, Larkin's 30(b)(6) witness expressly acknowledged that Larkin would not have done so, that the idea "made no sense," given the delicate nature of a da Vinci system. *See* p. 12 above. The hospitals that did experiment with Restore (none of them plaintiffs here) had to bring Intuitive in after the fact to fix what Restore had broken. Bair Dec. ¶¶ 10-18.

Moreover, given the limited nature of what any third party *could* do, it would have made no economic sense for most customers – including these plaintiffs – to employ them. Plaintiffs, like most da Vinci owners, had comprehensive service contracts with Intuitive, which covered both the few things Restore claimed to be able to do and the many things it could not do. So if Franciscan, for example, had hired Restore to perform one of the few repairs Restore was able to do, it would have been paying Restore *extra* for work that was already fully covered under its Intuitive contract. Only a customer that had no service contract and paid for each repair individually could even theoretically have benefited from Restore's services. Although all da Vinci customers had the *right* to exercise that option, very few chose to do so – only a tiny fraction of the sales. *See id.* ¶ 5. Franciscan and Valley chose comprehensive service contracts, as did Larkin for much of the period. *Id.* ¶ 9. Larkin's contract lapsed in 2020, but, as stated above, its corporate representative has acknowledged that it would not have used third-party service.

Plaintiffs attempt to rescue this claim by offering an opinion from their expert that, notwithstanding the fact that none of these plaintiffs had any interest in buying services from a third party, they might nonetheless have benefited if one assumes that a substantial number of *other* da Vinci owners would have had such an interest, because this would have exerted downward pressure on the price of Intuitive's service contracts. But, as Intuitive has shown in its *Daubert* motion on this expert, *see* Dkt. No. 126 at 12-13, this wholly speculative theory is entirely lacking in record support. There is no evidence that any appreciable number of customers *would* have opted for Restore's highly degraded service option. This speculative theory is not enough to prove that *these plaintiffs* suffered antitrust injury as a result of an alleged inability to pursue an alternative in which they had no interest. *See Elison*, 11 F.4th at 203; *Amer. Express Anti-Steering Rules Antitrust Litig.*, 19 F.4th 127 at 141-42.

C. Intuitive's Conduct Was Supported by Legitimate Justifications.

Plaintiffs' antitrust claims fail for the additional reason that Intuitive's challenged conduct was supported by legitimate pro-competitive justifications. Under each of plaintiffs' theories, Intuitive's conduct can be found to violate the antitrust laws *only* if it injured competition and was not supported by non-pretextual justifications. *American Express*, 138 S. Ct. at 2284.[11] As the Supreme Court has explained, a plaintiff must first show that the challenged restraint has a substantial anticompetitive effect that harms consumers in a relevant market, after which "the burden shifts to the defendant to show a procompetitive rationale for the restraint. If the defendant makes this showing, then the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means." *Id.* The alternative must be "a significantly (not marginally) less restrictive means for achieving the same procompetitive benefits[.]" *NCAA v. Alston*, 141 S. Ct. 2141, 2164 (2021); *see also Epic Games, Inc. v. Apple Inc.*, 559 F. Supp. 3d 898, 1040 (N.D. Cal. 2021). The analysis of plaintiffs' Section 2 claims is "essentially the same." *Qualcomm*, 969 F.3d at 991. Courts can review claims under Sections 1 and 2 simultaneously, and "if … [the] court finds that the conduct in

[11] This framework applies to all of plaintiffs' claims, including those under Section 1 for tying and exclusive dealing, as well as those under Section 2. *Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1197 (9th Cir. 2012); *Fed. Trade Comm'n v. Qualcomm Inc.*, 969 F.3d 974, 991, 1003 (9th Cir. 2020); *see also Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 42 (2006) (rule of reason applies to claims involving patented products).

question is not anticompetitive under § 1, the court need not separately analyze the conduct under § 2." *Id.*

For multiple reasons, including those discussed above, injury to lawful competition – and resulting antitrust injury to plaintiffs – does not exist here. But even if plaintiffs could carry their threshold burden, their claims would fail because the undisputed facts show that Intuitive's conduct was supported by legitimate justifications.

Plaintiffs regularly forget that they have no basis under the *antitrust* laws to challenge the use limits themselves. Antitrust is about *competition*, *id.* at 993, and were it not for the feature that disables an EndoWrist after its final approved use, the only "competition" plaintiffs claim could have existed – intervention by third parties to hack that software and bypass the use limits – could not exist even in theory. Thus, in a but-for world without use limits, competition would not be enhanced. In any event, the undisputed facts establish that Intuitive had legitimate reasons for designing its instruments as it did.

The antitrust laws will not condemn a defendant that had a "reasonable basis to conclude that its [challenged] actions were necessitated by concrete factual imperatives recognized as legitimate by the regulatory authority." *Phonetele, Inc. v Amer. Tel. & Tel. Co.*, 664 F.2d 716, 737-38 (9th Cir. 1981); *see Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 55 n.23 (1977) (recognizing legitimate justifications arising from federal and state laws requiring "that manufacturers assume direct responsibility for the safety and quality of their products"); *Taylor v. Volkswagen of Amer., Inc.*, 2009 WL 1011631 (W.D. Wash. Apr. 14, 2009) (granting summary judgment where restrictions were justified by, *inter alia*, ensuring that vehicles met certification and operational standards of the countries in which sold).[12] This principle derives from a general understanding that "the proper role of antitrust courts is to

[12] *See also In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 12 (1st Cir. 2020) (regulatory justification defense can defeat antitrust claim if defendant's decision was reasonable and made in good faith); *Southern Pac. Commc'ns Co. v. Amer. Tel. & Tel. Co.*, 740 F.2d 980, 1009-10 (D.C. Cir. 1984) (same); *cf. Robertson v. Sea Pines Real Est. Cos.*, 679 F.3d 278, 292 (4th Cir. 2012) (challenged restrictions "may serve to ensure compliance with state regulations … rather than to exclude lower-priced competition"); *In re Wyoming Tight Sands Antitrust Cases*, 1990 WL 155542, at *3 (D. Kan. Sept. 6, 1990) ("evidence of regulatory compliance" relevant to whether challenged activities were procompetitive).

accommodate the peculiar circumstances under which regulated entities operate." *Phonetele*, 664 F.2d at 743.[13]

There is no evidence to rebut Intuitive's showing that it had a "reasonable basis" for concluding that EndoWrist use limits were needed – and that FDA, as the governing regulatory authority, agreed. The regulatory regime governing Class II medical devices like EndoWrists requires a manufacturer to demonstrate that its devices are subject to "special controls," evaluated through the 510(k) process, that provide a reasonable assurance of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(B); *see* Cahoy Dec. Ex. 1 ¶¶ 35-37, 142-46. For EndoWrists, those measures include the use limits, which were (a) designed to address a known vulnerability of the instruments, (b) supported by extensive testing, and (c) carefully reviewed by FDA over the course of more than two decades. After reviewing these submissions, FDA cleared the instruments as "limited use" devices. Rosa Dec. ¶ 31; Cahoy Dec. Ex. 1 ¶¶ 75-101. That the use limits were justified by the existing technical record, and regarded as such by FDA, was reinforced when FDA insisted to prospective remanufacturers that their attempts to tamper with those limits required a full new round of testing and FDA clearance. (*See* pp. 15-16 above.)

Moreover, the determination that use limits were needed, the evaluation of methods through which they should be determined and implemented, and the accompanying fundamental design choices for EndoWrists all occurred more than two decades ago, long before there was any suggestion that third parties might try to "compete" by hacking the devices. Rosa Dec. ¶¶ 29-32, 37. They were adopted at a time when Intuitive was a new entrant struggling to convince customers to accept a brand-new technology, *id.* ¶ 23, and at that time it could have had no market power that would allow it to force buyers to accept unwanted restrictions, Smith Dec. Ex. 1 ¶¶ 139, 180. Given these facts, no credible claim of pretext could be made. *See Epic Games*, 559 F. Supp. 3d at 1038 (upholding asserted justifications where the plaintiff failed to show them to be pretextual).

Nor can plaintiffs carry their burden of demonstrating the existence of a substantially less restrictive alternative that would be "virtually as effective" and could be implemented "without

[13] Most courts, including the Ninth Circuit, characterize a defendant's regulatory compliance as a "defense" rather than a source of blanket immunity. *E.g.*, *Phonetele*, 664 F.2d at 737. It is therefore discussed here under the justification defense prong of the Supreme Court's standard test.

significant increased cost." *Id.* at 1041 (citation omitted). Intuitive was under no obligation to design its product with use limits that would be the "least restrictive alternative." *Alston*, 141 S. Ct. at 2161 ("[A]ntitrust law does not require businesses to use anything like the least restrictive means of achieving legitimate business purposes," and "courts should not second-guess degrees of reasonable necessity so that the lawfulness of conduct turns upon judgments of degrees of efficiency."). The most plaintiffs offer on this point is their expert's speculation that Intuitive might have designed EndoWrists to apply *different* criteria to manage use on an individual basis, such as the period of time the instrument is in active use and the force with which it is applied during surgery. But this is pure theory on his part; he does not identify a *practical* way to implement it in a working instrument. (Intuitive's *Daubert* motion on this expert is at Dkt. No. 122.) And since no such design exists, he can offer no basis to conclude that such a design – even if it worked and even if its safety could be verified – would consistently require EndoWrists to be replaced substantially less often, making the use limits substantially less restrictive. *See Brooke Grp. Ltd.*, 509 U.S. at 242 (unsupported expert opinion cannot defeat summary judgment).

Given the legitimacy of the use limits (as demonstrated by FDA clearance of EndoWrists as "limited use" devices), Intuitive's efforts to ensure that the limits were not circumvented, including the letters sent to customers, are supported by the same justifications. Those letters, which stressed the absence of required FDA clearance for the remanufacturing that was occurring and the associated patient safety implications, furthered Intuitive's general obligation to ensure that its products (including the da Vinci systems to which the remanufactured EndoWrists were attached) were operated in full compliance with FDA requirements. They also fulfilled Intuitive's broader duty to take reasonable steps to protect against injuries that could arise from misuse of its products. *See, e.g.*, *Hiner v. Deere & Co.*, 340 F.3d 1190, 1193-94 (10th Cir. 2003); *Lewis v. Tallahassee*, 2006 WL 231291, at *2 (N.D. Fla. Jan. 30, 2006); *Wright v. Stang Mfg. Co.*, 54 Cal. App. 4th 1218, 1235 (1997).

For this independent reason, Intuitive is entitled to summary judgment on plaintiffs' claims concerning remanufactured EndoWrists.

D. Plaintiffs Cannot Show Any Material Adverse Impact on Competition in Their Alleged "Market" for Da Vinci Service.

Even if one accepts, *arguendo*, that there is a cognizable antitrust "relevant market" for da Vinci service, plaintiffs cannot show any material adverse impact on competition resulting from any conduct of Intuitive – other than conduct plaintiffs have already conceded to be lawful. Customers are not required to purchase service from Intuitive. *See* Bair Dec. ¶ 5. Most (including the plaintiffs here) have chosen to enter into comprehensive service contracts, but that is primarily because Intuitive does not make its proprietary service tools and software available to third parties, who are accordingly unable to provide most of the service customers need. Plaintiffs long ago disclaimed any challenge to Intuitive's decision not to share that intellectual property. *See* Dkt. No. 69, at 2. And as discussed above (at pp. 20-21), there is no evidence that enough customers would have had any reason to opt for the limited (and highly degraded) service Restore was able to provide so as to cause its unavailability to have any material competitive impact. The Court left this issue open in ruling on Intuitive's motion to dismiss, but to defeat summary judgment plaintiffs must come forward with actual *evidence*, and they have none.

Intuitive's contracts disclaimed any obligation to provide service to fix problems caused by a third party (although Intuitive *did* fix problems that Restore caused, *see* Bair Dec ¶¶ 10-18). But considerably more restrictive disclaimers than this are regularly upheld, and there are no special circumstances here warranting a different result. *See, e.g.*, *Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 405 (3d Cir. 2016); *United Asset Coverage, Inc. v. Avaya Inc.*, 409 F. Supp. 2d 1008, 1046 (N.D. Ill. 2006).

E. Plaintiffs' Motion for Summary Judgment Should Be Denied.

If the Court grants summary judgment for Intuitive, it need not consider plaintiffs' summary judgment motion. Either way, plaintiffs' motion should be denied. On the FDA clearance issue, plaintiffs' motion should be denied for the same reasons set forth in Part III.A.1 above.

Plaintiffs' motion for partial summary judgment on issues of market definition and market power should also be denied. In an antitrust case, determining the relevant market is a fact-intensive inquiry, involving "identification of the field of competition: the group or groups of sellers or producers who have actual or potential ability to deprive each other of significant levels of business…. This definitional

process is a factual inquiry for the jury; the court may not weigh evidence or judge witness credibility." *Thurman Indus., Inc. v. Pay 'N Pak Stores, Inc*., 875 F.2d 1369, 1374 (9th Cir. 1989). The definitions of markets that are "relevant" to plaintiffs' claims, as well as the question of whether Intuitive possesses market power in any such market, are subjects of substantial factual disputes between the parties, based on evidence that includes extensive opinions from Intuitive's economic expert, whose qualifications and opinions plaintiffs have not challenged on *Daubert* grounds. *See* Smith Dec. Ex. 1 ¶¶ 68-180. Although plaintiffs' expert disagrees with many of those opinions, this dispute is alone sufficient to require denial of plaintiffs' motion for summary judgment on these issues. *See Arista Networks, Inc. v. Cisco Sys. Inc*., 2018 WL 11230167, at *8 (N.D. Cal. May 21, 2018) (summary judgment not appropriate on monopoly power because "there is an abundance of evidence that is disputed or that weighs against [plaintiff's] contention that [defendant] has monopoly power," including competing expert evidence).

1. Genuine Issues of Material Fact Preclude a Finding that Da Vincis and EndoWrists Are Separate Products.

Plaintiffs begin by seeking a partial summary judgment ruling that da Vinci robots and EndoWrists are sold in separate product markets, even though it is undisputed that both are necessary elements of the da Vinci system and neither is purchased for any other purpose. Under *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2 (1984), the existence of distinct product markets depends upon "the character of the demand for the two items." *Id.* at 19. There must be "a sufficient demand for the purchase" of the allegedly tied product "separate from" the tying product "to identify a distinct product market." *Id.* at 21-22. Merely showing that there was some limited demand for EndoWrists from third parties does not suffice to demonstrate that EndoWrists are in a separate market. *See* Smith Dec. Ex. 1 ¶ 98 & n.284. The extent of any such demand is a highly disputed factual question. Numerous plaintiff witnesses confirmed that if FDA took the position that remanufactured EndoWrists required FDA clearance they would not use them. (*See* p. 18 above.)

Intuitive's economic expert, Dr. Smith, has analyzed the record and opined that the da Vinci Surgical System – which includes both the da Vinci robot and the EndoWrists – is sold as a single product. Smith Dec. Ex. 1 ¶¶ 68-102. The contract the customer signs for the da Vinci Surgical System provides that the customer will purchase EndoWrists from Intuitive on a going forward basis. *See, e.g.*,

Cahoy Dec. Ex. 11 at -5490, Ex. 12 at -6318. Materials provided to the customer in advance of purchase address the lifetime cost of the *system*, including EndoWrists. Rosa Dec. ¶¶ 14-21 & Ex. 1 at -1263, -1274, -1305-09.[14] Whether there are separate product markets here is *at least* a disputed issue of fact.

2. There Are Disputed Issues of Material Fact on Questions of Market Definition and Market Power.

Plaintiffs have also failed to show the absence of genuine issues of material fact regarding whether Intuitive possessed monopoly power in a relevant antitrust market. Monopoly power may be proven through direct evidence of "restricted output and supracompetitive prices" or inferred from indirect evidence that "a defendant owns a dominant share" of the relevant antitrust market. *Rebel Oil Co., Inc. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995). Plaintiffs have insufficient proof of either to support summary judgment.

A plaintiff seeking to prove monopoly power through direct evidence faces a high bar: it must show both "restricted output and supracompetitive prices." *Id.*; *see also In re Glumetza Antitrust Litig.*, 2021 WL 1817092, at *7 (N.D. Cal. May 6, 2021) (noting that the court was aware of no appellate decisions affirming a market power holding based on direct evidence). Plaintiffs come nowhere near to meeting that bar. Plaintiffs claim that Intuitive's profit margins (measured based on marginal costs, without taking account of R&D and other fixed costs) were "high," *see* Pl. Mot. at 13 & n.8, but courts readily recognize that "[c]ertain deviations between marginal cost and price, such as those resulting from high fixed costs, are not evidence of market power," especially in an industry that requires intensive ongoing investments in R&D, *United States v. Eastman Kodak Co.*, 63 F.3d 95, 109 (2d Cir. 1995); *see also Kaiser Found. v. Abbott Lab'ys*, 2009 WL 3877513, at *9 (C.D. Cal. Oct. 8, 2009) (recognizing that pricing difference between brand and generic drug did not reflect supra-competitive pricing, as generics do not incur the substantial R&D expenses incurred by brand companies). Intuitive's economist explains this. Smith Dec. Ex. 1 ¶¶ 155-57, 166-72. Moreover, plaintiffs' expert admits that he is not relying on evidence of restricted output for his market power analysis. Cahoy Dec.

[14] Another surgical robotic manufacturer, CMR Surgical, sells its surgical system as an integrated product, confirming that other market participants view their systems and instruments as a single product. Smith Dec. Ex. 1 ¶¶ 89-90.

Ex. 70 at 267:19-268:10; *see also Epic Games*, 559 F. Supp. 3d at 1030-31 (finding lack of evidence of decreased output "fatal in demonstrating monopoly power").

Plaintiffs must therefore prove that Intuitive had monopoly power through indirect evidence, which requires them to define a relevant market and demonstrate that Intuitive had high market shares in that market. *Rebel Oil Co., Inc.*, 51 F.3d at 1421. This fact-intensive exercise is rarely suitable for summary judgment, as it requires evaluation of, among other things, the actual nature of supply and demand for the products at issue and what reasonable substitutes are available in the marketplace. *See Thurman Indus.*, 875 F.2d at 1374; *see also Arista*, 2018 WL 11230167, at *6-7 (denying motion for summary judgment on the grounds that there were triable issues of fact with respect to market power where experts offered differing views).

Plaintiffs' proffered evidence that some surgeons have a preference for robotic surgery in certain situations is insufficient to take this question from the jury. This is especially so given the extensive evidence that surgeons are trained to perform the same surgeries through open, lap, and robotic procedures, that they choose which procedure is best for each patient, and that these decisions often involve economic comparisons across the surgical modalities. *See, e.g.*, Smith Dec. Ex. 1 ¶¶ 111, 118-19; Cahoy Dec. Ex. 51 at 38:10-39:4. Based on this and other evidence, Intuitive's economic expert has concluded that the relevant market must include *at least* laparoscopy surgery. Smith Dec. Ex. 1 ¶¶ 103-36. Indeed, laparoscopy remains the majority surgery of choice for many types of surgery. *Id.* Table 1. And there is no evidence that Intuitive possesses a sufficient share of that broader market to give it market power.

Plaintiffs go on to assert a second time, *see* Pl. Mot. at 17-18, that there is a separate product market consisting of original and remanufactured EndoWrists in which Intuitive has monopoly power. As discussed above, there is a disputed issue of fact as to whether there is a separate market for EndoWrists. And there is extensive record evidence that remanufactured EndoWrists are not "functional" and "economic" substitutes for new EndoWrists, as plaintiffs claim. *Id.* To the contrary, as shown above, there is plentiful evidence that customers – including plaintiffs here – would not view

remanufactured, uncleared EndoWrists, with their heightened risk of failure, as economic substitutes for new instruments.[15]

Accordingly plaintiffs are not entitled to summary judgment that Intuitive has monopoly power in their alleged market.

IV. CONCLUSION

For the reasons set forth above, the Court should enter summary judgment for Intuitive on all of plaintiffs' claims and deny plaintiffs' motion for partial summary judgment.

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[15] Plaintiffs call their proposed market one for "EndoWrist repair and replacement." But there is no evidence of any market demand for genuine "repair" of EndoWrists; nor has any third party expressed interest in offering repair services. The only potential substitutes plaintiffs identify are EndoWrists remanufactured to bypass their use counters. And there is a serious question about how much genuine demand has ever existed – or would ever exist – for that in the absence of FDA clearance.

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